Opening Statement of the Honorable Joe Pitts
Subcommittee on Health
Hearing on "Examining Federal Regulation of Mobile Medical Apps and Other Health Software"
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(As Prepared for Delivery)

In the last few years, health information technologies, including mobile medical applications (apps), electronic health records, personal health records, computerized health care provider order entry systems, and clinical decision support have transformed the provision of health care in this country.

In September of this year, the Food and Drug Administration (FDA) put forward a proposal, in the form of final guidance, indicating that software was a medical device for the purposes of regulation—except that software is not a medical device.

To regulate it as such, the FDA has said it will use discretion to decide which software to regulate. Except that no matter what Dr. Shuren tells this committee here today, there is no guarantee that his successor won't go back on this guidance tomorrow.

While guidance is a valuable tool for the FDA, there is a significant limitation: certainty. What stands today could change tomorrow.

Patients and industry have told us that the FDA's involvement and guidance was a good thing – there was too much ambiguity around the issue and companies needed to know what the FDA intended to do. In addition, many believe the FDA acted to the best of its ability with the only tool available to them – its medical device definition.

But they also are telling Congress that we need to give FDA new tools that create regulatory certainty not just today but also tomorrow. That certainty can start with properly defining what these technologies are for the purposes of regulation.

Rep. Blackburn and her colleagues on both sides of the aisle have outlined an approach that would give the FDA a new tool – a 21st century definition – to regulate a 21st century technology.

The SOFTWARE Act is a starting place and an opportunity to begin a dialogue with thought leaders like the FDA. Rep. Blackburn and five of her colleagues – Democrats and Republicans – have put forward one way to modernize the FDA so that it is ready to meet the challenge it has so far recognized it needs to meet. I commend her for her thoughtful approach to this issue and for her leadership.

Dr. Shuren, I stand ready to pledge this committee's support to help you modernize the agency in a way that makes sense for patients, for industry, and for the Agency. I hope you take this offer seriously, and will agree to work with us toward a goal we all share.

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